Testimony

Regarding Proposals Seeking To Amend the Class I Fluid Milk Product Definition

Federal Register Volume 70, Number 69
Proposed Rules Page 19012-19015

By: John Bunting, Delhi, NY 13753

On behalf of National Family Farm Coalition

Hearing Convening on June 20, 2005, Pittsburgh Pennsylvania
Held by: USDA/Agricultural Marketing Service/Dairy Division

My name is John Bunting. I am a dairy farmer in Delaware County, NY and I also write for a dairy publication. Today I am testifying on behalf of National Family Farm Coalition (NFFC) in opposition to amending the definition of fluid milk. The NFFC was founded in 1986 and represents family farm and rural groups in 30 states whose members' face the challenge of the deepening economic recession in rural communities caused primarily by low farm prices and the increasing corporate control of agriculture. The dairy subcommittee has members from coast to coast.

NFFC has taken an active role in the dairy protein debate. NFFC submitted testimony to the U.S. International Trade Commission hearing on dairy proteins. NFFC submitted a citizens petition to the Food and Drug Administration (FDA) in April of 2004 requesting the Food and Drug Administration to Notify State and Federal regulators of GRAS requirements of Milk Protein Concentrate (2004P-0202/CP1).[i]

The context of this hearing is particularly troubling in that it represents a significant step backwards in the nearly one hundred year struggle in the effort to gain public confidence in the quality of dairy products. Indeed, the language of 7 USC 608 (c) 18 states the need to "insure a sufficient quantity of pure and wholesome milk". In 1934, under Nebbia v. New York, the U.S. Supreme Court (291 U.S. 502) clearly stated that milk was clothed in public interest. The Court wrote, "Thus, understood, "affected with a public interest" is the equivalent of "subject to the exercise of the police power"

Milk Protein Concentrate neither a legal food ingredient, nor considered milk under FDA rules

From the very beginning the use of Milk Protein Concentrates (MPC) has been a flagrant violation of the public's interest and the rule of law. In spite of wide spread usage, there is no GRAS (**G**enerally **R**ecognized **A**s **S**afe) for MPCs. According to the FDA "Under sections 201(s) and 409 of the Act, and FDA's implementing regulations in 21 CFR 170.3 and 21 CFR 170.30, the use of a food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food."[ii]

MPCs were not used in food prior to 1958 and therefore subject to "scientific procedures" in determining GRAS. Under a "Freedom of Information Request" response to me on August 13 2003, the FDA stated, "We have searched our files and find responsive information for the scientific studies on human safety and consumption of ultrafiltered milk/milk protein concentrate."

There is at least one very good reason for this; there is no definition for milk protein concentrate. Nothing can be studied scientifically which cannot be defined.

U.S Customs made an attempt to define MPC's and failed. In September 2002 National Milk Producers Federation (NMPF) petitioned Customs for a definition. In Customs decision we read:

> Many of the comments contend that your position, which limits coverage of the Note to products produced by ultrafiltration, is not supported by the language of the Note. These comments point out that when Congress was drafting the Note, it could have used restrictive language to achieve the result you urge. However, this was not done.
>
> These commenters state that in the food industry, the term "milk protein concentrates" is commonly used to refer to a wide variety of products of varying composition. These products are manufactured to specification to render them suitable for specific end uses in the food industry. In addition, they point out that certain milk protein concentrates are obtained by a combination of ultrafiltration and blending, while other products contain milk proteins that are isolated from milk by other processes such as precipitation. They contend that products containing 40 percent or more protein by weight have more protein than milk and are thus milk protein concentrates. They also note that if Congress intended the provision to be limited to the total milk proteinate that was the subject of the previous Customs ruling, it would not have en-acted the broad language of Additional Note 13 and would not have set the milk protein threshold as low as 40 percent.
>
> Upon consideration of the petition and the comments submitted, Customs agrees with the comments received that the Note does not restrict MPCs to any particular method of manufacture. Rather, the Note speaks to "any" complete milk protein concentrate which contains a specified protein percentage by weight. The use of the term "any" suggests that a broad rather than restrictive reading of the note was intended. The Note does require that the protein be "complete" which, according to the Note, requires that it contain casein and lactalbumin. However, the Note neither requires that the proteins be in the same proportion as they are found in milk, nor does it specify relative percentages of the protein components. It requires only that the source of the proteins be milk, that casein and lactalbumin be present, and that they constitute 40 percent or more, by weight, of the product.[iii]

Clearly, the dairy food industry wants to be totally free and unrestricted in calling anything it so chooses MPC's. Clearly then, we are not talking about "amending" any definition of milk. This hearing is, in reality, about **eliminating** any definition of milk in the interest of processor profit.

Under GRAS regulations, FDA allows individual determination for each product produced. This is not done because the sole purpose of MPC use is because processors profit from use of lower-cost ingredients. To test for each product would severely reduce or eliminate profit. Therefore, all MPC use is a reprehensible violation of the rule of law.

Making this matter even worse is the tacit complicity of FDA in MPC use. While FDA correctly states use of MPC's in standardize products is illegal, they say use of MPC's in non-standardized products is allowed. FDA fails to mention that GRAS certification is required in non-standardized products.

Certainly, industry could correct this problem by clearly defining MPC's and running scientific safety studies. The fact that this could be done and has not been done suggests there may indeed be a dark unsafe side to MPC's.

No imported MPCs are produced in compliance with Grade A Pure Milk Ordinance

In addition to the troubling disregard for GRAS regulations, these proposals require the abandonment and tossing out of the Grade "A" Pasteurized Milk Ordinance (PMO).[iv]

The PMO requires:

> "Each dairy farm, milk plant, receiving station, milk tank truck cleaning facility and transfer station whose milk or milk products are intended for consumption within ...of...[1] or it's jurisdiction, and each bulk milk hauler/sampler who collects samples of raw milk for pasteurization, for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station and each milk tank truck and its appurtenances shall be inspected by the Regulatory Agency prior to the issuance of a permit."

USDA Foreign Agricultural Service trade database list over 40 countries which have imported Chapter 35 dairy proteins, which include casein, caseinates and casein MPCs.

Do those proposing the use of these dairy based products, such as MPCs and caseinates. really expect farms in Belarus, the Ukraine and Peoples Republic of China will be inspected by a qualified U.S. agency? That, of course, would be preposterous. "M-A-83 - Grade "A" Powdered Dairy Blends as Ingredients, etc."[v] requires, "If a powdered blend is to be used as an ingredient in the production of a Grade "A" product from an IMS listed plant, the blend must be labeled Grade "A" and the plants where the Grade "A" dairy powders are manufactured and the facility where the powder is blended and packaged must each have an acceptable IMS listing." How do the proponents of these proposals, or USDA, propose to guarantee that Powdered Dairy Blends and Ingredients will be sourced from PMO-approved sources?

From "nutrient content claim" to labeling to the PMO definition of "concentrated milk", all of these and more would have to be thrown out if the proposals advocating the use high protein products are incorporated into USDA Federal Milk Order rules and regulations.

Anyone who might suggest, limiting these ingredients to only domestically produced products is sadly ignorant of the power of the WTO (World Trade Organization). Rules promulgated by the WTO are not as likely to be ignored as U.S. rules.

Will these proposals allow for foreign dairy farmers to siphon off Federal Milk Order pool revenues?

Finally, there is the bottom line. The Federal Orders are about payment. In the May 2005 issue of *The Progressive Dairyman,* Elwin Hollon, a DFA Vice President spoke of this hearing. The article said, referring to statements by Hollon, "The main emphasis is on new forms of milk proteins, like milk protein concentrate (MPC), that are used to create new fluid products. Hollon says if a farmer's milk is used to make a product that competes with Class I, then the farmer should be paid for Class I."

What farmer and where? All indications are that MPCs's cannot be made profitably in the U.S. MPC would dictate use of imported MPCs's. Is anyone thinking farmers in India or New Zealand will be getting blend price for their milk? Furthermore, as Mr. Hollon must surely know, the domestic MPC producing Dariconcepts plant in Portales, N.M. pays Class IV price for MPC production.[vi] The USITC report *Conditions of Competition for Milk Protein Products in the U.S. Market,* Investigation No. 332—453 mentions several advantageous of the Portales plant and says, "Even with these advantages, purchasers of MPC from the Dairiconcepts facility still pay a premium over the price of imported MPC to provide the facility with a return that is equivalent to the return on SMP."[vii]

In reality, the bottom line is to have MPCs's accepted as just "Good ole' milk" which they are not. These proposals are merely a continuation of the deception associated with the use of MPCs's. A recent example of the deception is found in U.S. patent application number 20050123647 , which proposes use of MPC's to make cheese, we find not once but, twice, "Other GRAS (Generally Regarded As Safe) ingredients common to cheese making process may be added at any suitable stage..." Despite widespread claims of safety MPCs's to this day are not GRAS. And, MPC's are not milk and have no place in the definition of fluid milk.

To summarize, I speak in opposition to all proposals which would classify as Class I (fluid) ingredients in the use of dairy-based beverages which do not currently meet Federal Milk Order requirements for 6.5% nonfat dairy solids.

- Milk Protein Concentrates do not meet FDA food safety rules, under GRAS specifications, as legal food ingredients.
- Milk Protein Concentrates and caseins, which are not manufactured to any degree in the U.S. are imported in vast quantities. The sources of the foreign dairy ingredients do not meet U.S. Pure Milk Ordinance standards for Grade A farm, plant, and milk truck haulers. Nor do various dairy personnel from such nations comply with U.S. PMO rules.
- If USDA were to implement these proposals, there could be a revenue outflow from the Federal Milk order revenue pools to foreign dairy producers.
- If USDA were to implement these proposals, the Department would be in violation of its legislative mandate to provide "pure and wholesome milk." "Milk" in the form of illegal MPCs and foreign-sourced dairy ingredients that do not comply with the U.S. Pure Milk Ordinance and FDA's GRAS specifications can neither be pure or wholesome.

By all reason and logic, it is a farce that USDA should even these issues to the level of a national Federal Milk Order hearing.

[i] http://www.fda.gov/ohrms/dockets/dailys/04/apr04/042904/04P-0202-ACK00001-vol1.pdf
[ii] http://www.cfsan.fda.gov/~dms/grasguid.html
[iii] http://www.cbp.gov/linkhandler/cgov/toolbox/legal/bulletins_decisions/bulletins_2003/vol37_07302003_no31/37genno31.ctt/37genno31.pdf Page 6
[iv] http://www.cfsan.fda.gov/~ear/pmo01-2.html
[v] http://vm.cfsan.fda.gov/~ear/M-A-83.html

[vi] http://hotdocs.usitc.gov/docs/pubs/332/pub3692.pdf
[vii] ibid Page 5-20

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

John Bunting
2362 Peakes Brook Road
Delhi, NY 13753

AUG 13 2003

F03-8050

Dear Mr. Bunting:

In response to your request of June 9, 2003 for copies of all scientific studies on human safety and consumption of Ultra Filtered Milk/Milk Protein Concentrate.

Information regarding ultra filtered milk/milk protein concentrate may be obtained from FDA/Dockets Management Branch/5630 Fishers Lane /Rockville, MD 20857 under the following Dockets: 99P-5198 and 00P-0586.

____Enclosed are the records you requested.

__XX__We have searched our files and find no responsive information for scientific studies on human safety and consumption of ultra filtered milk/milk protein concentrate.

____Your request is also being referred to one of our component offices.

____In order to help reduce processing time and costs, certain material has been deleted from the record(s) furnished to you because a preliminary review of the records indicated that the deleted information is not required to be publicly disclosed. If, however, you desire to review the deleted material, please make an additional request at the following address: Food and Drug Administration, Freedom of Information Staff, HFI-35, 5600 Fishers Lane, Rockville, MD 20857. Should the Agency then deny this information, you would have the right to appeal such denial. Any letter of denial will explain how to make this appeal.

Charges will be included in a monthly invoice if your request(s) total more than $15.00. If your monthly total is LESS than $15.00, the material is free. Please DO NOT send payment until you receive an invoice for the total monthly fee.

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THE ABOVE TOTAL MAY NOT REFLECT THE FINAL CHARGES FOR THIS REQUEST.

Sincerely yours,

FOI OFFICER
Executive Operations Staff
Center for Food Safety
and Applied Nutrition

NO Enclosure

June 17, 2005

UNITED STATES DEPARTMENT OF AGRICULTURE
FOREIGN AGRICULTURAL SERVICE
HS 4-DIGIT IMPORTS

AREA/COUNTRIES OF ORIGIN AND COMMODITIES IMPORTED CONSUMPTION IMPORTS		JANUARY - DECEMBER QUANTITIES					JANUARY - APRIL COMPARISONS		
		2000	2001	2002	2003	2004	2004	2005	%CHNG
ARGENTINA	CASEIN, CASEINATES 3501 MT	10.2	0.0	0.0	0.0	0.0	0.0	0.0	--
AUSTRALIA(*)	CASEIN, CASEINATES 3501 MT	5,407.1	5,015.3	7,867.8	14,340.1	12,290.6	4,589.7	3,595.4	-21.66
AUSTRIA	CASEIN, CASEINATES 3501 MT	0.0	152.1	0.0	0.0	0.0	0.0	0.0	--
BELGIUM-LUXEMBOURG(*)	CASEIN, CASEINATES 3501 MT	269.9	89.2	20.0	40.0	0.0	0.0	0.0	--
BELARUS	CASEIN, CASEINATES 3501 MT	20.0	118.5	225.8	162.4	122.2	102.2	40.6	-60.27
BULGARIA	CASEIN, CASEINATES 3501 MT	0.0	20.0	0.0	0.0	0.0	0.0	0.0	--
CANADA	CASEIN, CASEINATES 3501 MT	0.0	20.7	15.3	0.0	35.4	11.0	20.0	81.82
CHINA, PEOPLES REPUB	CASEIN, CASEINATES 3501 MT	430.4	392.5	200.7	565.6	1,475.0	633.1	482.1	-23.85
COSTA RICA	CASEIN, CASEINATES 3501 MT	4.8	0.0	0.0	5.0	8.1	0.0	0.0	--
DENMARK(*)	CASEIN, CASEINATES 3501 MT	2,131.0	2,064.0	1,804.4	2,605.0	2,175.7	745.2	546.9	-26.61
DOMINICAN REPUBLIC	CASEIN, CASEINATES 3501 MT	0.9	0.0	0.0	0.0	0.0	0.0	0.0	--
IRELAND	CASEIN, CASEINATES 3501 MT	24,328.2	20,470.3	20,095.4	22,550.0	22,446.0	4,166.8	5,450.5	30.81
ESTONIA(*)	CASEIN, CASEINATES 3501 MT	500.0	200.0	1.0	434.0	10.5	0.0	0.0	--
EL SALVADOR	CASEIN, CASEINATES 3501 MT	1.0	0.0	0.0	0.0	0.0	0.0	0.0	--
CZECH REPUBLIC	CASEIN, CASEINATES 3501 MT	0.0	0.0	0.0	273.4	78.0	19.5	0.0	--
FRANCE(*)	CASEIN, CASEINATES 3501 MT	14,586.0	9,731.2	8,329.4	8,102.0	9,026.0	3,001.8	3,622.7	20.68
GERMANY(*)	CASEIN, CASEINATES 3501 MT	6,636.5	6,598.9	6,564.7	9,002.3	5,276.7	2,061.4	907.4	-55.98
HONG KONG	CASEIN, CASEINATES 3501 MT	0.0	0.0	17.5	5.0	0.0	0.0	0.0	--
HUNGARY	CASEIN, CASEINATES 3501 MT	666.6	346.8	219.4	565.9	268.9	88.4	56.7	-35.86
INDONESIA	CASEIN, CASEINATES 3501 MT	0.0	34.0	85.0	0.0	0.0	0.0	0.0	--
INDIA	CASEIN, CASEINATES 3501 MT	5,336.0	4,351.1	6,490.2	4,809.8	5,753.0	2,410.3	4,271.0	77.20
ITALY(*)	CASEIN, CASEINATES 3501 MT	59.2	24.6	24.8	24.5	0.0	0.0	0.0	--
JAPAN	CASEIN, CASEINATES 3501 MT	35.2	0.0	0.0	0.0	12.2	0.0	0.0	--
KAZAKHSTAN, REPUBLIC	CASEIN, CASEINATES 3501 MT	100.0	0.0	30.7	20.0	0.0	0.0	0.0	--
LATVIA(*)	CASEIN, CASEINATES 3501 MT	40.0	100.0	160.0	200.8	80.0	80.0	20.0	-75.00
LITHUANIA(*)	CASEIN, CASEINATES 3501 MT	17.0	0.0	380.0	180.0	0.0	0.0	0.0	--
MEXICO	CASEIN, CASEINATES 3501 MT	0.3	0.0	0.0	11.0	80.5	11.3	19.2	69.91
NIGER	CASEIN, CASEINATES 3501 MT	1.0	0.0	0.0	0.0	0.0	0.0	0.0	--
NETHERLANDS	CASEIN, CASEINATES 3501 MT	7,503.7	7,396.5	7,352.7	8,157.8	9,072.3	3,395.3	3,294.6	-2.97
NORWAY(*)	CASEIN, CASEINATES 3501 MT	39.0	281.0	0.0	137.1	278.0	117.6	19.6	-83.33
NEW ZEALAND(*)	CASEIN, CASEINATES 3501 MT	40,226.6	40,725.0	31,639.1	35,786.4	33,131.7	11,414.3	17,548.3	53.74
POLAND	CASEIN, CASEINATES 3501 MT	973.5	3,651.2	2,883.7	4,545.5	4,869.3	1,242.3	1,107.8	-10.83
PHILIPPINES	CASEIN, CASEINATES 3501 MT	0.0	0.0	40.0	0.0	0.0	0.0	0.0	--
RUSSIAN FEDERATION	CASEIN, CASEINATES 3501 MT	4,783.6	1,753.0	2,361.2	1,042.7	111.8	11.8	0.0	--
SOUTH AFRICA, REPUBL	CASEIN, CASEINATES 3501 MT	0.0	0.0	0.1	0.0	0.0	0.0	0.0	--
SPAIN	CASEIN, CASEINATES 3501 MT	100.0	0.0	40.0	0.0	0.0	0.0	0.0	--
SWITZERLAND(*)	CASEIN, CASEINATES 3501 MT	44.6	0.0	5.4	0.0	193.5	1.6	171.0	10587.50
TRINIDAD AND TOBAGO	CASEIN, CASEINATES 3501 MT	0.0	1.0	0.0	0.0	0.0	0.0	0.0	--
TAIWAN	CASEIN, CASEINATES 3501 MT	0.0	35.4	0.0	6.6	20.0	0.0	0.0	--
UNITED KINGDOM	CASEIN, CASEINATES 3501 MT	2,994.0	1,160.3	1,055.4	1,372.5	1,821.5	679.2	540.0	-20.49
UKRAINE	CASEIN, CASEINATES 3501 MT	2,552.1	2,095.0	2,128.9	1,883.6	2,686.5	299.7	237.8	-20.65
URUGUAY	CASEIN, CASEINATES 3501 MT	200.2	0.0	0.0	0.0	0.0	0.0	0.0	--
TOTAL	MT	119,998.5	106,827.5	100,038.7	116,828.8	111,323.4	35,082.4	41,951.6	19.58

Data Source: Department of Commerce, U.S. Census Bureau, Foreign Trade Statistics
(*) denotes a country that is a summarization of its component countries.

**** WARNING ****

Users should use cautious interpretation on QUANTITY reports using mixed units of measure. Commodity groups on a value report will reflect a total of all statistics for each commodity in the group in DOLLARS, whereas a QUANTITY line item will show statistics on the greatest number of like units of measure for grouped commodities.

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
FDA Prime Connection

M-a-83 - Grade "A" Powdered Dairy Blends as Ingredients, etc.

HHS:PHS:FDA:CFSAN:OFP:DCP:MSB

200 C Street, S.W.
Washington, DC 20204

M-a-83

September 1, 1994

TO: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

FROM: Chief, Milk Safety Branch (HFS-626)

SUBJECT: Grade "A" Powdered Dairy Blends as Ingredients of Other Grade "A" Dairy Products.

This memorandum was issued on May 2, 1994, and was subsequently accepted by the NCIMS Executive Board and the FDA in accordance with agreements between the NCIMS and FDA related to the issuance of interpretative memoranda.

Powdered dairy products such as nonfat dry milk, whey protein concentrate, casein, lactose, whey, etc. are blended, packaged and sold as an ingredient for use in the production of dairy products. This memo is written to clarify when these dry blends of powdered dairy products may be labeled Grade "A", when they may be used as ingredients in Grade "A" dairy products, and when the facilities used to produce these blends must be IMS listed.

Powdered dairy blends maybe labeled Grade "A" and used as ingredients in Grade "A" dairy products, (such as cottage cheese dressing mixes or starter media for cultures used to produce various Grade "A" cultured products) if they meet the requirements of this memorandum.

If used as an ingredient in Grade "A" products such as those listed above, blends of dairy powders must be blended under conditions which meet all applicable Grade "A" requirements. Grade "A" powder blends must be made from Grade "A" powdered dairy products except that small amounts of functional ingredients (total of all such ingredients shall not exceed 5% by weight of the finished blend) which are not Grade "A" are allowed in Grade "A" blends when the finished ingredient is not available in Grade "A" form (i.e. sodium caseinate).

This is similar to the existing FDA position that such dairy ingredient in small cans of freeze dried starter culture need not be Grade "A".

If a powdered blend is to be used as an ingredient in the production of a Grade "A" product from an IMS listed plant, the blend must be labeled Grade "A" and the plants where the Grade "A" dairy powders are manufactured and the facility where the powder is blended and packaged must each have an acceptable IMS listing.

Copies of this memorandum are enclosed for your distribution to District Milk Specialists, state milk regulatory agencies, State Laboratory Evaluation Officers and State Milk Rating Officers in your region. This memorandum is also available on the FDA Prime Connection computer bulletin board system, and should be widely distributed to representatives of the milk industry and other interested parties.

to be tested to prevent reintroduction of the disease. Vigilance in TB surveillance at slaughter plants is critical in preventing this disease from becoming re-established in the state. The interim rule is available at www.aphis.usda.gov/ppd/rad/webrepor/all.html.

Hearing on proposed federal changes to Class I fluid milk definition

USDA will hold a national public hearing to consider proposed changes to the product definition for Class I fluid milk in all federal milk marketing orders. Dairy Farmers of America (DFA) has proposed the changes.

Eldin Hollon, vice president of fluid marketing and economic analysis for the cooperative, says they want to make sure producers are getting a Class I price for their milk. "In today's dairy industry, we've gotten really good at taking a hundred pounds of milk when it comes out of a cow, taking it apart into all of its components, and then recombining those components into products consumers want."

Hollon says the industry is so good at this that they can formulate products that compete with fluid milk but end up being called Class II, "because of the nature of the definition."

The main emphasis is on new forms of milk proteins, like milk protein concentrate (MPC), that are used to create new fluid products. Hollon says if a farmer's milk is used to make a product that competes with Class I, then the farmer should be paid for Class I. "Certainly somebody who is making those types of products today would have some opposition because they would like to have those monies in their bottom line instead of in the dairy farmer's bottom line."

The hearing will be June 20, 2005, at the Sheraton Station Square Hotel in Pittsburgh, Pennsylvania. Written comments will also be accepted either via mail or email. **PD**

United States), you argue that they show a clear intent of Customs to classify only products which are manufactured by means of ultrafiltration in non-quota provisions. In your view, these rulings served as the impetus for Congressional modification of the TSUS. To support your position you provided language from the 1984 Senate Finance Committee Report on the Omnibus Tariff and Trade Measures (S. Prt 98–219) which created three new provisions in the TSUS to provide for: Whey Protein Concentrate (Item 118.35); Lactalbumin (Item 118.40); and Milk Protein Concentrate (Item 118.45). The Committee report describes total milk proteinate as being "a soluble milk proteinate in which casein and undenatured whey products are isolated as a single protein complex."

That Committee Report also contained a proposed TSUS Headnote defining milk protein concentrate as "any milk protein concentrate that is 40 percent or more protein by weight." You contend that the report demonstrates that only ultrafiltrated milk protein concentrates were intended to be included within the non-quota tariff provision created by Congress. When the HTSUS was adopted, the non-quota treatment of MPCs was carried forward to the subheading at issue. However, you concede that Congress did not include any language in either the TSUS Headnote, or the HTSUS Additional U.S. Note, which explicitly identifies any particular manufacturing process as being required for MPC.

As stated above, goods are classified under the HTSUS according to the terms of the headings and relevant section and chapter notes and by applying the GRIs in order. You have contended that the MPC products in the identified rulings should be classified in heading 0402, HTSUS. Heading 0402, HTSUS, provides for: Milk and cream, concentrated or containing added sugar or other sweetening matter. "Concentrated" milk is defined by the U.S. Food and Drug Administration (FDA) as being "the liquid food obtained by partial removal of water from milk." The products which are the subjects of the disputed rulings are not concentrated milk, but rather are products which consist of milk constituents. The ENs to heading 0404, HTSUS, provide, in pertinent part, "The heading also covers fresh or preserved products consisting of milk constituents, which do not have the same composition as the natural product, provided they are not more specifically covered elsewhere. Thus the heading includes products which lack one or more natural milk constituents, milk to which natural milk constituents have been added (to obtain, for example, a protein-rich product)." As such, milk protein concentrates are described by the terms of heading 0404 and not those of heading 0402. Accordingly, they are ineligible for classification in heading 0402 and we must now determine the correct subheading for the products within heading 0404, HTSUS.

The manufacturers and importers buy and sell the products under consideration as "Milk Protein Concentrates." We have determined that the products are goods of heading 0404, HTSUS. We must now determine whether the products are included within the scope of the legal definition of milk protein concentrate contained in Additional U.S. Note 13 to Chapter 4.

A number of the comments received in response to the 516 Notice discussed the terms of Additional U.S. Note 13. Many of the comments contend that your position, which limits coverage of the Note to products produced by ultrafiltration, is not supported by the language of the Note. These comments point out that when Congress was drafting the Note, it could have used restrictive language to achieve the result you urge. However, this was not done.

These commenters state that in the food industry, the term "milk protein concentrates" is commonly used to refer to a wide variety of products of varying composition. These products are manufactured to specification to render them suitable for specific end uses in the food industry. In addition, they point out that certain milk protein concentrates are obtained by a combination of ultrafiltration and blending, while other products contain milk proteins that are isolated from milk by other processes such as precipitation. They contend that products containing 40 percent or more protein by weight have more protein than milk and are thus milk protein concentrates. They also note that if Congress intended the provision to be limited to the total milk proteinate that was the subject of the previous Customs ruling, it would not have en-

acted the broad language of Additional Note 13 and would not have set the milk protein threshold as low as 40 percent.

Upon consideration of the petition and the comments submitted, Customs agrees with the comments received that the Note does not restrict MPCs to any particular method of manufacture. Rather, the Note speaks to "any" complete milk protein concentrate which contains a specified protein percentage by weight. The use of the term "any" suggests that a broad rather than restrictive reading of the note was intended. The Note does require that the protein be "complete" which, according to the Note, requires that it contain casein and lactalbumin. However, the Note neither requires that the proteins be in the same proportion as they are found in milk, nor does it specify relative percentages of the protein components. It requires only that the source of the proteins be milk, that casein and lactalbumin be present, and that they constitute 40 percent or more, by weight, of the product.

None of the conditions you urge such as retention of "fully functional properties" and that the proteins not be "denatured", which you have indicated are requirements for inclusion in the subheading 0404.90.10, are specified in the text of Additional U.S. Note 13 to Chapter 4. Had Congress intended the subheading to be limited to only those products which meet the standards you specify, it could have drafted the provision accordingly. However, the text that was adopted does not contain any of the narrow restrictions you describe. Moreover, there is nothing in the legislative history that demonstrates an intent to limit the provision to ultrafiltrated products. Finally, as many commenters pointed out, and the study performed by the General Accounting Office on this issue made clear, the term "milk protein concentrates" is used in commerce to refer to a class of products much broader than those produced by ultrafiltration. For example, the study states that products known as milk protein concentrates produced in Canada are made by blending milk proteins. (General Accounting Office, *Report to Congressional Requesters, Dairy Products: Imports, Domestic Production, and Regulation of Ultra-filtered Milk*, GAO-01-326, March 2001, at 7). Tariff terms are presumed to reflect their commercial meaning. (*Nylas Trading Co. v. United States*, 37 CCPA 71 (1949); *Carl Zeiss, Inc. v. United States*, 195 F.3d 1375 (1999), citing *Simod Am. Corp. v. United States*, 872 F.2d 1572 (Fed. Cir. 1989).

For a product to be eligible for classification in subheading 0404.90.10, HTSUS, it must be a concentrate. You argue that the term refers to a product that has had liquids removed from it to make it stronger, and that only ultrafiltered products satisfy this requirement. Customs itself initially considered this view in 2001, when, as part of a Notice of proposed revocation, it stated: "the common dictionary meaning of the words 'milk protein concentrate' would be a protein product derived from milk in which the milk protein content has been intensified or purified by the removal of 'foreign or inessential' milk constituents, such as water, minerals and lactose." (See *Customs Bulletin and Decisions*, Vol. 35, No. 40, October 3, 2001).

Comments received in response to that Notice noted that products known in the trade as milk protein concentrates were in fact produced by a variety of methods other than ultrafiltration. They argued these products, e.g., a blend of skim milk and whey protein concentrates or caseinates, were concentrates since they were dairy products whose milk protein content was higher than that found in milk.

Upon further consideration, Customs agrees that such products may be considered concentrates within the meaning of the provision. These products consist of milk constituents whose protein content has been intensified by blending with a concentrated milk protein such as whey protein concentrate or caseinates.

In that same proposed revocation, Customs referred to an International Dairy Federation publication of May 1992, as the basis for the statement that "The dairy industry has specific terminology and parameters when referring to milk protein concentrate."

While that statement reflected certain information before Customs at the time of the proposal, comments received thereafter revealed that there is no standard of identity for MPC recognized under the *Codex Alimentarius* or other international nongovernmental organizations. Similarly, there is no recognized commercial standard for these products. Milk protein concentrates contain varying amounts of milkfat, pro-